Special 510(k) Summary

MAY 3 1 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510K summary prepared: February 15th, 2013

Submitter's Name, address, telephone number, a contact person:

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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/Proprietary Name:	PHT-6500 (PHT-60CFO)
Common Name:	Dental Computed Tomography X-ray System
Classification Name:	System, X-ray, Tomography, Computed , Dental(21CFR 892.1750, Class II)
Product Code:	OAS

Predicate Device:

Manufacturer:	Vatech Co., Ltd
Device Name:	PHT-6500 (PHT-60CFO)
510(k) Number:	K122606

Device Description:

PHT-6500 (PHT-60CFO), a dental radiographic imaging system, consists of three image acquisition modes; panoramic, cephalometirc and cone beam computed tomography. Specifically designed for dental radiography of the teeth or jaws, PHT-6500 (PHT-60CFO) is a complete dental X-ray system equipped with x-ray tube, generator and dedicated SSXI detector for dental panoramic, cephalometric and cone beam computed tomographic radiography.

The dental CBCT system is based on CMOS digital X-ray detector. CMOS CT detector is used to capture radiographic diagnostic images of oral anatomy in 3D for dental treatment such as oral surgery or implant. The device can also be operated as the panoramic and cephalometric dental x-ray system based on CMOS X-ray detector. The proposed device is available with two X-ray generator options.

A pair of CT sensor and Pano sensor are assembled together, back to back, and fixed mechanically to the rotating X-ray gantry, facing the X-ray tube from the opposite side. Based on the choice of a modality, between CT and panorama, the mechanically attached sensors rotate automatically so an appropriate type of sensor is facing the X-ray tube for exposure.

The type of CT sensor attached to the equipment determines the model name. The model name, PHT-6500, refers to the equipment mounted with Xmaru0712CF, and Xmaru1215CF Plus SSXI detector whereas PHT- 60 CFO model refers to the equipment mounted with Xmaru1215CF Master Plus and Xmaru1524CF Master Plus SSXI detector.

Indication for use:

PHT-6500 (PHT-60CFO) is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360°

rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and x-ray technicians.

Summary of the technological characteristics of the device compared to the predicate device:

The new device described in this special 510(k) submission is an upgraded version of the predicate device with the same model name, the same indications for use and technical characteristics. Table 1 summarizes the technological characteristics of the new vs. the predicate device.

Table 1. Comparison of new PHT-6500 (PHT-60CFO) and the predicate device

Characteristic	Proposed Vatech Co., Ltd. *PHT-6500 (PHT-60CFO)*	Predicate Vatech Co., Ltd. *PHT-6500 (k122606)*
510(k) number	-	K122606
Indications for use	PHT-6500 (PHT-60CFO) is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry . The device is operated and used by physicians, dentists, and x-ray technicians.	PHT-6500 (PHT-60CFO) is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry . The device is operated and used by physicians, dentists, and x-ray technicians.
Performance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography
Input Voltage	AC 100-240 V	AC 100-120/200-240 V
Tube Voltage	50-99 kV	50-90 kV
Tube Current	4 ~16 mA	4 ~10 mA
Exposure Time	0.7 – 24 s	0.7 – 24 s

X-ray Source	D-052SB OPX/105		D-052SB
X-ray Generator	DG-07C11T2 (for D-052SB) DG-07C11C1 (for OPX/105)		HDG-07B10T2
Focal Spot Size	0.5 mm		0.5 mm
Slice Width	0.1 mm min.		0.1 mm min.
Total Filtration	2.8 mmAl		2.8 mmAl
Chin Rest	Equipped Headrest		Equipped Headrest
Performance Specification	Computed tomography		Computed tomography
Mechanical	Compact design		Compact design
Electrical	LDCP logic circuit		LDCP logic circuit
Software	DICOM 3.0 Format compatible		DICOM 3.0 Format compatible
2D Image Viewing Program	EasyDent		EasyDent
3D Image Viewing Program	Ez3D Plus		Ez3D Plus
Anatomical Sites	Maxillofacial		Maxillofacial
Image Receptor	***Computed Tomography*** *(Flat Panel Detector)*		Xmaru0712CF	Xmaru0712CF
			Xmaru1215CF Plus	Xmaru1215CF Plus
			Xmaru1215CF Master Plus	Xmaru1215CF Master Plus
			Xmaru1524CF Master Plus	-
	Panoramic *(CMOS photodiode array)*		Xmaru1501CF	Xmaru1501CF
	Cephalo Metric *(CMOS photo diode array)*	*Scan Type*	Xmaru2301CF	Xmaru2301CF
			Xmaru3001CF	-
		One Shot Type	1210SGA	1210SGA
			910SGA	910SGA
			1417PGA	-
Size of Active	***Xmaru0712CF***		Max. 8 x 8 cm	Max. 8 x 8 cm

Imaging Area		***Xmaru1215CF Plus***	Max. 12 x 9 cm	Max. 12 x 9 cm
		Xmaru1215CF Master Plus	Max. 10 x 8 cm	Max. 12 x 9 cm
		Xmaru1524CF Master Plus	Max. 16 x 10 cm	-
		Xmaru1501CF	150.4 x 6 mm	150.4 x 6 mm
		Xmaru2301CF	230.4 x 5.9 mm	230.4 x 5.9 mm
		Xmaru3001CF	307.2 x 5.9 mm	
		910SGA	260 x 227 mm	260 x 227 mm
		1210SGA	325 x 264 mm	325 x 264 mm
		1417PGA	422.7 x 357.6 mm	
Pixel Resolution	***CT***	***Xmaru0712CF***	3.5 lp/mm	3.5 lp/mm
		Xmaru1215CF Plus	3.5 lp/mm	3.5 lp/mm
		Xmaru1215CF Master Plus	5.0 lp/mm - 2x2 binning	5.0 lp/mm - 2x2 binning 2.5 lp/mm - 4x4 binning
		Xmaru1524CF Master Plus	5.0 lp/mm - 2x2 binning	-
	Pano	***Xmaru1501CF***	5 lp/mm	5 lp/mm
	Ceph	***Xmaru2301CF***	5 lp/mm	5 lp/mm
		Xmaru3001CF	5 lp/mm	-
		1210SGA	3.9 lp/mm	3.9 lp/mm
		910SGA	3.9 lp/mm	3.9 lp/mm
		1417PGA	3.9 lp/mm	-
Pixel Size	***CT***	***Xmaru0712CF***	140 x 140 ㎛	140 x 140 ㎛
		Xmaru1215CF Plus	140 x 140 ㎛	140 x 140 ㎛
		Xmaru1215CF Master Plus	99 ㎛ - 2x2 binning	99 ㎛ - 2x2 binning 198 ㎛ - 4x4 binning
		Xmaru1524CF Master Plus	99 ㎛ - 2x2 binning	-

	Pano	***Xmaru1501CF***	100 x 100 μm	100 x 100 μm
	Ceph	***Xmaru2301CF***	100 x 100 μm	100 x 100 μm
		Xmaru3001CF	100 x 100 μm	-
		1210SGA	127 x 127 μm	127 x 127 μm
		910SGA	127 x 127 μm	127 x 127 μm
		1417PGA	127 x 127 μm	-

Summary of Performance Testing:

The PHT-6500 (PHT-60CFO) dental computed tomography X-ray system described in this special 510(k) is identical to the predicate device in its indications for use, performance, materials, safety characteristics, image viewing program and accessory components

Furthermore, the following information further substantiates the substantial equivalence between two devices:

- The fundamental technological characteristics of the subject and predicate device were the same.
- Laboratory and clinical performance testing using the same test protocols as used for the cleared detectors was evaluated by qualified individuals employed by the sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.
- The intended use of the modified device, as described in the labeling, has not changed as a result of the labeling modification(s).

For both devices, the differences are as follows.

1. *New SSXI detectors, Xmaru1524CF Master Plus (CBCT mode), 1417PGA (One Shot Ceph mode) and Xmaru3001CF (Scan Ceph mode) for the newly upgraded* PHT-6500 (PHT-60CFO) *have different active areas compared with k122606, the predicate device.*
2. *Change to Free Input Voltage: For the predicate device, changing the input voltage from 110V to 200V would require separate tools and electrical works whereas the new device is equipped with a newly designed power board which is capable of handling the input power between 100 V and 240 V without a separate tool or electrical modification.*
3. *The proposed PHT-6500 is available with two different X-ray tube and generator options.*

To evaluate the safety, a series of safety tests are conducted for each generator according to the IEC Standard. Moreover, a separate image evaluation is performed for each X-ray generator which is considered as one of critical components affecting the quality of radiographic images and imaging performance of the device. The maximum rating chart for each new X-ray tube and generator option is described in the Device Description (page. 19 ~ 20). The graph indicates the exposure time range for various voltage and current settings.

4. *For proposed PHT-6500 (PHT-60CFO), a new generator for X-ray tube has the capacity to generate more tube current and tube voltage than the predicate device. Moreover, the maximum irradiation condition for each capture mode is defined differently by diversifying the operating range of the generator specifications.*

Non-clinical test and clinical consideration test were conducted for each new sensor of PHT-6500 (PHT-60CFO) compared with its predicate device with regard to Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE) and Noise to Power Spectrum (NPS). Based on the Non-Clinical Test results, even though the pixel size and active area of the new SSXI detectors are different, the diagnostic image quality of new sensors is equal or better than that of the predicate device and there is no significant difference in efficiency and safety.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (Ed. 2, 2000), IEC 60601-1-3 (Ed. 1, 1994), IEC 60601-2-7 (Ed. 2, 1998), IEC 60601-2-28 (Ed. 1, 1993), IEC 60601-2-32 (Ed. 1, 1994) and IEC 60601-2-44 (Ed. 2, 2002) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review.

PHT-6500 (PHT-60CFO) meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for

the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed for the newly proposed device. A separate clinical image evaluation is performed for each X-ray generator which is considered as one of critical components affecting the performance of a radiographic imaging device.

Acceptance test and CT image evaluation report according to IEC 61223-3-4 and IEC 61223-3-5 were performed. A separate imaging evaluation is performed for each X-ray generator which is considered as one of critical components affecting the performance of a radiographic imaging device.

DICOM Conformance Statement, image viewing SW validation reports, biocompatibility evaluation report of the newly proposed device are identical to those of the predicate device. The newly proposed device also shares identical X-ray detectors with the predicate device. Therefore, DICOM conformance statement, biocompatibility evaluation report, image viewing SW validation reports and the non-clinical consideration report for detectors same between the proposed and predicate device are not included in this submission.

All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that the newly upgraded PHT-6500 (PHT-60CFO) is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2013

VaTech Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberley Lane
HOUSTON TX 77079

Re: K130432
Trade/Device Name: PHT-6500 (PHT-60CFO)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: May 6, 2013
Received: May 9, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130432

Device Name: PHT-6500 (PHT-60CFO)

Indications for Use:

PHT-6500 (PHT-60CFO) is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry . The device is operated and used by physicians, dentists, and x-ray technicians..

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130432